

REMARKS

In the last Office Action, the Examiner maintained the rejection of claims 10-15, 17-22, 25-32, 34-38, and 46-62 under 35 U.S.C. § 102(b) and made a new rejection of the claims under § 103(a). In addition, a new provisional obviousness-type patenting rejection in light of copending U.S. application 09/973,013 was made. Finally, the Office made several new rejections under 35 U.S.C. § 112, second paragraph.

Applicants traverse the finality of the new rejection under 35 U.S.C. § 103(a), in light of Fields, et al., because this rejection was not made before, and was not due to Applicants' previous claim amendments or previously submitted information. M.P.E.P. § 706.07(a). In their response to the previous Office Action, Applicants traversed the rejection under 35 U.S.C. § 102(b) that the Office made on the basis of Fields, et al. Therefore, there was no claim amendment to prompt a new rejection under § 103 on the basis of Fields, et al., and, accordingly, Applicants respectfully request that the finality of this rejection be withdrawn.

Rejections under 35 U.S.C. § 102(b)

The Office maintained the rejection of the claims as being anticipated by Fields, et al. Specifically, the Office noted that Fields, et al. disclose that "the method of the present invention can be applied more generally to any detectable function requiring separable domains of an amino acid sequence which can be reconstituted." The Office asserted that this statement would encompass enzymatic activity. See Paper No. 19 at pgs. 4-5.

Applicants have amended claims 10, 13, 14, and 25-27, so that they, and the claims from which they depend, recite that the enzymatic activity is chosen from two enzymes: adenylate cyclase or guanylate cyclase. This amendment is supported on

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page 15, lines 16-18 of the specification. None of the claims reciting these enzymes is anticipated by Fields, et al., because the passage cited by the Office does not recite the adenylate cyclase or guanylate cyclase enzymes. In fact, there is no guidance in the passage from Fields, et al. as to what a "detectable function requiring separable domains" might be. The only guidance provided is a description of the GAL4 transcriptional activator that has separable domains for DNA binding and transcriptional activation. See Fields, et al. at col. 7, lines 43-49. Transcriptional activators such as GAL4, though, are not enzymes, and are not adenylate cyclase or guanylate cyclase. Therefore, the claims, as amended are not anticipated by Fields, et al., and Applicants respectfully request that the rejection be withdrawn.

Rejections under 35 U.S.C. § 103(a)

The Office also rejected the claims as being rendered obvious by Fields, et al. See Paper No. 19 at pgs. 4-5. Applicants assert that, as amended, the claims are not obvious in light of Fields, et al. because this reference does not provide any motivation to one skilled in the art to use the adenylate cyclase or guanylate cyclase enzymes in the claimed method of selecting a molecule of interest. Not only does Fields not recite the use of adenylate cyclase, guanylate cyclase, or any other enzyme, the disclosure of a transcriptional activator, GAL4, would not direct one skilled in the art to use any enzymes or the enzymes cited in the claims, because transcriptional activators are not enzymes and are not adenylate cyclase or guanylate cyclase. Therefore, Fields et al. does not render the claimed invention obvious under 35 U.S.C. § 103(a), and Applicants respectfully request that the rejection be withdrawn. "When obviousness is based on a particular prior art reference, there must be a showing of a suggestion or motivation to

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modify the teachings of that reference." *B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*, 72 F.3d 1577, 1582, 37 U.S.P.Q.2d 1314, 1318 (Fed. Cir. 1996). Here, however the Office has shown no motivation to modify the teachings of Fields to use transcriptional activators in a method for selecting a molecule of interest.

Provisional Obviousness-type doublepatenting rejection

Claims 10-15, 17-22, 25-32, 34-38, and 46-62 were provisionally rejected under the judicially created doctrine of obviousness-type doublepatenting because the Office asserted that they were unpatentable over claims 10-23 and 24-38 of copending application No. 09/917,013. See Paper No. 19 at pg. 6. Applicants note that no patent has been issued from application No. 09/917,013, and so there has been no extension of the "right to exclude" granted by a patent, which serves as the basis for a double patenting rejection. *In re Van Ornum*, 686 F.2d 937, 943-44, 214 U.S.P.Q. 761, 766-67 (C.C.P.A. 1982). Accordingly, Applicants traverse this provisional rejection and respectfully request that it be withdrawn.

Rejections under 35 U.S.C. § 112, second paragraph

The Office rejected claims 10 and 25 as being vague and indefinite because of the phrase "amplifying a signal generated by . . ." in step (3) of each claim. See Paper No. 19 at pg. 7, lines 8-11. The Office was unsure about which signal was amplified and how this amplification fits in with the other steps of the claimed method.

Applicants respectfully traverse this rejection, and point out the description provided in the specification that explains how signal amplification works in the claimed invention. Specifically, the specification explains:

The present invention further relates to a method of selecting a molecule of interest, which is capable of binding to a target

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ligand, wherein the interaction between the said molecule of interest and the said target ligand is detected with a signal amplification system according to the invention, by means of generating a signal amplification and triggering transcriptional activation.

Specification at pg. 6, lines 28-34. The specification further explains that:

Another aspect of the present invention consists in a method of selecting a molecule of interest, which is capable of binding to target ligand, wherein the interaction between the said molecule of interest and the said target ligand is detected with a signal amplification system according to the invention, by means of signal amplification which triggers transcriptional activation, and is quantified by measuring the synthesis of the signaling molecule or the expression of the reporter gene.

Specification at pg. 17, lines 14-22. Furthermore:

The signal amplification corresponds to the production of a signaling molecule. This signaling molecule is any molecule capable of leading to a signaling cascade reaction.

In a preferred embodiment of the invention, the signaling molecule corresponds to the synthesis of cAMP.

In another preferred embodiment of the invention, the signaling molecule corresponds to the synthesis of cGMP.

Specification at pg. 17, lines 26-32. From these passages in the specification it is clear that the signal recited in the claims is a molecule "capable of leading to a signaling cascade reaction", such as cAMP or cGMP, or other similar molecules. Signal amplification occurs when the molecule of interest interacts with the target molecule. Thus, when the fragments of adenylate cyclase or guanylate cyclase are brought together by the molecule of interest and the target ligand they will produce a signaling molecule, such as cAMP or cGMP, or similar molecule, as recited in steps (1) and (2). These steps are the precursors to amplification of the signal, as indicated in step (3).

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Therefore, the identity of the signal and the role of signal amplification as recited in the claims and supported in the specification is defined.

The Office also questioned how, in claim 25, one could determine that a given substance partially inhibited the interaction between the molecule of interest and the target ligand, because it asserted that the transcriptional activation in step (3) is "an all or nothing phenomenon." See Paper No. 19, pg. 7, lines 11-13. Applicants first note that claim 25 does not recite partial inhibition of the interaction, but that claim 31 does, and that the Office may have intended to discuss this claim, instead. Also, Applicants note that transcriptional activation is step (4) of claims 25 and 29, instead of step (3).

As to the substance of the Office's inquiry, Applicants point out that in contrast to the Office's assertion, transcriptional activation is not "an all or nothing phenomenon." This is reflected in Applicants' description of their invention, where the interaction of the molecule of interest and the target ligand are "quantified by measuring the synthesis of the signaling molecule or the expression of the reporter gene." Specification at pg. 17, lines 20-22. The amount of expression or transcriptional activation can be quantified, and thus it is not an all or nothing phenomenon because the magnitude is known when it is quantitated. Therefore, Applicants respectfully request that this rejection under 35 U.S.C. § 112 be withdrawn.

The Office also rejected claims 10 and 25 as being vague and indefinite because of the term "capable of." See Paper No. 19, pg. 14-16. Applicants have deleted this term from the claims and therefore request that the rejection on this ground be withdrawn.

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The Office rejected claims 10, 13, 17, 21, and 25-38 as being vague and indefinite because of the term "interaction." See Paper No. 19, pg. 7, lines 17-18. Applicants have deleted this term from the claims, and added the term "binding" instead. This term is supported in the specification at page 15, lines 12-15. Accordingly, Applicants request that this rejection be withdrawn.

In addition, the Office rejected claim 17 because it considered the use of the term "detected by signal amplification" to be unclear. See Paper No. 19, pg. 7, lines 19-21. As explained in the specification, "[s]ignal amplification corresponds to the production of a signaling molecule," pg. 17, lines 26-27, where this molecule, for example cAMP or cGMP, is "capable of leading to a signaling cascade reaction". Pg. 17, line 28. Furthermore, molecules, such as cAMP and cGMP and other similar molecules, are known to be products of the enzymes recited in the claims, adenylate cyclase and guanylate cyclase, and therefore it would be clear to one skilled in the art how these molecules are produced. Finally, as explained above, the role of this signal is explained in the specification, as well as in the steps of the claim, as providing a signal for quantitation itself, or for triggering transcriptional activation, which is then quantified. Because the term "detected by signal amplification" is clear, Applicants respectfully request that the rejection on this basis be withdrawn.

The Office also rejected claims 20 and 36 as being vague and indefinite due to the term "gene with a selectable phenotype" because the Office asserted that genes do not have "phenotypes." See Paper 19, pg. 8, lines 1-2. The claim term has been deleted and the term "encodes a protein with a selectable phenotype" has been added to the claims. Therefore, Applicants request that this rejection be withdrawn.

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The Office rejected claims 22 and 38 as being vague and indefinite due to the term "performed in a bacterial strain." This term has been amended to "performed in a bacteria", and Applicants request that the rejection be withdrawn.

In addition, the Office rejected claims 46 and 52 for reciting improper Markush language. These claims have been amended to replace the term "and" with the term "or" as indicated by the Office. Applicants respectfully request that the rejection on this ground be withdrawn.

The Office rejected claims 49 and 55 for a lack of antecedent basis for the term "color marker". Applicants have amended claims 49 and 55 to include the word "the" before the term "color marker", in reference to "a color marker" in claims 46 and 52, from which claims 49 and 55 depend, respectively. Applicants respectfully request that the rejection be withdrawn.

Finally, claim 60 was rejected as being vague and indefinite. Applicants have canceled this claim in this Amendment, thus obviating the rejection to it.

Applicants also note that the amendments to claims 46, 51, 52, and 57 are supported on page 18, lines 5-6, of the specification and do not add new matter.

In light of the foregoing amendments and explanations, Applicants respectfully request that all of the rejections under 35 U.S.C. § 112, second paragraph, be withdrawn.

Drawing objections

In addition to the Office's rejections of the claims, objections to the drawings were also made. Specifically, Figure 3 was required to be labeled as Figures "3A" and "3B". Subject to the Request for Approval for Drawing Change, submitted herewith,

Applicants have changed Figure 3 to indicate panels "3A" and "3B". Applicants have also amended the Brief Description of the Drawings in the specification to reflect this change in labeling. Therefore, Applicants respectfully request that the objection to the drawings be withdrawn.

Applicant respectfully request that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner, placing claims 10-15, 17-22, and 25-32, 34-38, 46-59, 61, and 62, in condition for allowance. Applicants submit that the proposed amendments of claims 10, 13-15, 17, 20-22, 25-32, 34-38, 46, 49, 52, and 55 do not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner, since all of the elements and their relationships claimed were either earlier claimed or inherent in the claims as examined. Therefore, this Amendment should allow for immediate action by the Examiner.

Furthermore, Applicants respectfully point out that the final action by the Examiner presented some new arguments as to the application of the art against Applicant's invention. It is respectfully submitted that the entering of the Amendment would allow the Applicants to reply to the final rejections and place the application in condition for allowance.

Finally, Applicants submit that the entry of the amendment would place the application in better form for appeal, should the Examiner dispute the patentability of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

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Respectfully submitted,

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Appendix

Attached are two Replacement Sheets for Figures 3A and 3B and two annotated sheets showing changes

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